

news

A global collaborative effort
against malaria in Africa



letter

Published by the Wellcome Trust

The Multilateral Initiative on Malaria (MIM) is an alliance of organisations & individuals concerned with malaria. It aims to maximise the impact of scientific research against malaria in Africa, through promoting capacity building & facilitating global collaboration & coordination.

Issue 3, December 1998

Welcome to the third issue of the MIM newsletter, and the first edition to be translated into French. Arrangements for the forthcoming MIM African Malaria Conference, to be held in Durban in March 1999, have been continuing apace, and the second meeting of the Steering Committee was held in Durban at the beginning of November. Provisional details of the format and content of the Conference were among the subjects discussed, and a brief report is included in the newsletter. Please note that if you wish to attend the conference you must register before 11 January.

Also in this issue we have an update from Julia Royall of the US National Library of Medicine, who reports on the latest activities of the MIM Communications Working Group (MIM CWG). The use of combinations of antimalarial drugs to delay the emergence of resistance is a subject which has aroused considerable interest in recent months, and we include an article by Prof. Nick White, Director of the Wellcome Trust Tropical Units in Thailand and Vietnam, and Dr Piero Oliaro of WHO/TDR, on developments in this area. To continue this theme, rational antimalarial drug policies in Africa is the subject of an article by Prof Oladapo Walker of AFRO/WHO. You will also find an extensive news section and a diary of forthcoming malaria-related meetings.

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MIM African Malaria Conference

In November, the MIM African Malaria Conference Steering Committee held its second meeting in Durban, to discuss the format, agenda and content of the conference, as well as logistical issues. Many of you should by now have received the second announcement flyer for the conference, which includes registration forms, details of accommodation, and how to apply for sponsorship. Those of you with access to the information superhighway will be able to download a copy of the flyer, including registration forms, in Adobe Acrobat pdf format from the following web sites: www.malaria.org; www.wellcome.ac.uk/mim

If you have not yet received your copy of the flyer, please inform the Conference Organising Committee:

MIM African Malaria Conference Organising Committee

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Members of the Steering Committee took the opportunity to inspect the Conference venue, the purpose-built International Convention Centre in Durban, and were very impressed by the excellent standard of facilities available to delegates.

Conference Format and Programme

As reported in Issue 2, the conference will be a forum to promote high quality research in partnership with African malaria control programmes. The conference is open to malaria researchers internationally and control programme personnel and health professionals across Africa.

The conference will be structured in such a way that plenary addresses by invited speakers will provide an overview of key malaria research issues in Africa. Breakout parallel sessions will offer an opportunity for the malaria research and control communities to come together to discuss mutual problems and solutions, and to identify critical research questions to be pursued in the future. Summary reports on the breakout sessions will be presented at the close of each day and in a final review at the end of the conference.

Keynote addresses will include amongst others:

- An overview of the progress of MIM
- Plans for 'Roll Back Malaria'
- Malaria vaccines & immunology
- Information for malaria control in Africa: are we ready?
- Economic impact of malaria in Africa
- Vector biology & control
- Needs & priorities for effective utilisation of antimalarial drugs

All plenary proceedings will be translated into English, French and Portuguese.

The final day of the conference will be devoted to a Workshop on Research Training & Capacity Development in Africa. The workshop will focus on research proposal development, submission and review, and on current opportunities and research capability strengthening needs in Africa.

A varied social programme is planned to provide ample opportunity for informal discussions between delegates.

We look forward to seeing many of you in March in Durban. However, please note the date of **11th January 1999** for final submission of abstracts, registration at hotels, and application for sponsorship!

Artemisinin derivatives in combination with other antimalarial drugs

Professor Nick White, Dr Piero Oliaro.

Worsening antimalarial drug resistance threatens to increase the already enormous morbidity and mortality from malaria in the tropics. There are few available antimalarials, and the cost of introducing drugs effective against chloroquine and antifolate resistant *Plasmodium falciparum* is unaffordable for most of the afflicted countries. Protecting the available drugs, and any newly introduced compounds, is therefore of the highest priority. The theoretical basis underlying the use of drug combinations in delaying/containing the emergence and spread of resistance in bacterial and viral infections is well known. WHO/TDR (with support from USAID under the new Infectious Disease initiative) and the Wellcome Trust have started a large research programme to evaluate antimalarial drug combinations. Central to this initiative is use of artemisinin derivatives, the most rapidly acting antimalarials discovered to date, as one of the combination partners. The initial objective is to establish the safety and efficacy of these combinations within two years. Then in the second phase field studies will be conducted to assess whether use of these combinations will delay antimalarial drug resistance, whilst translating the results of this research into policies.

TDR asked a group of experts, chaired by Prof N. White and managed by Dr P. Oliaro, to coordinate the WHO sponsored research activities on antimalarial drug resistance and policies. Between June-October 1998 this group generated a workplan and standard protocols following extensive consultation with leading experts and researchers. The initial focus of the research is on combinations of artesunate with either pyrimethamine/sulfa drugs, chloroquine or amodiaquine, and includes both pharmacokinetic and clinical studies. These comparative studies (and those being conducted by the Wellcome Trust sponsored research groups) are designed to provide the data that would be needed to change policies. Agreements with pharmaceutical companies are being made to secure the availability of study drugs. The first cross over interaction, pharmacokinetics and tolerability study in volunteers of artesunate and pyrimethamine/sulfadoxine has been completed; drug levels are being measured. Candidate sites to conduct efficacy and tolerability treatment studies in outpatients are being considered for support by TDR. Whilst each study is designed to have sufficient statistical power to stand alone, raw data will be pooled for integrated summaries of efficacy and tolerability. The first randomised, double-blinded, placebo controlled clinical study in The Gambia has already started enrolling patients.

Progress on Connectivity at MIM Sites

Ms Julia Royall

"What a pleasure for us and our collaborators to sit in our offices and browse the Web sites, being in contact with the

world in a few seconds, looking for the hidden world. What a great potential we are discovering." Dr. Yeya Touré, Director, Malaria Research and Training Center, Bamako, Mali.

Dr. Touré's testament reveals at once the excitement of African scientists and the potential that Internet access holds for scientific research. Since June of this year, he and his colleagues at the MRTC have had access to the Internet and the WorldWide Web through microwave technology. The equipment (including a local area network on site), installation, and training were funded by the U.S. National Institute of Allergy and Infectious Diseases/National Institutes of Health (NIAID/NIH), National Library of Medicine/NIH (NLM/NIH), and the World Bank.

This story from Mali is the first chapter in the work of the Multilateral Initiative on Malaria Communications Working Group (MIM CWG), chaired by the National Library of Medicine. Featured prominently are the major MIM objectives - support for African scientists, the ability of malaria researchers to connect with one another and sources of information, as well as the creation of new collaborations and partnerships - all of which reflect the spirit of the '97 meeting in Dakar.

The initial meeting of the MIM/CWG was held in January 1998 at the NLM/NIH in Bethesda, Maryland. In attendance were malaria research scientists, health information professionals, telecommunications experts and representatives of the major MIM funding agencies. In keeping with the underlying goal of supporting a broad spectrum of basic and operational malaria research needs, the researchers requested communications and connectivity capabilities sufficient to provide, at a minimum: robust and reliable e-mail, links to other research sites, access to full text journal articles, database searching, exchange of large files and mapping data, and timely access to electronic information resources worldwide.

In addition to the malaria research site in Bamako, Mali, the MIM/CWG endorsed five more locations for the initial connectivity phase. They are: in Kenya, the Centers for Disease Control/Kenya Medical Research Institute (CDC/KEMRI) site in Kisumu and the Wellcome Trust/KEMRI site in Kilifi, and in Tanzania, three sites of the National Institute of Medical Research in Dar es Salaam, Ifakara, and Amani. In several instances, sites have been provided with computer equipment and training, but since the majority of them are in relatively remote locations, traditional means of connecting to the Internet are not viable due to unreliability or bandwidth restrictions.

Subsequently, NLM supported site visits and assessments, consultancies, evaluation and testing of the extant technology. Related issues of user training, in-country licensure of technology, and allowances for future technological advances (such as predicted worldwide availability of low-cost commercial satellite systems) all figured in the development of a draft implementation plan by the MIM/CWG.

The plan recommends immediate use be made of the affordable technologies now available to provide high-speed and reliable information and communication links in order to yield timely results in improving researchers' ability to do co-operative research and disseminate their results.

Recommended technologies are VSAT, which uses a geostationary satellite and a small earth station, and microwave, which uses radio waves. The latter is less expensive but is limited to line of sight transmission. The MIM sites that wish to operate a radio or VSAT link will have to gain permission from the relevant in-country authority.

With the Mali model fully operational, NLM/NIH has stepped forward with an offer to fund the upfront equipment purchase and installation costs at these five sites, if partner funders can commit to support ongoing operational costs.

Sustainability is an essential ingredient if lasting connectivity is to be achieved for these research sites. In the case of the CDC/KEMRI site in Kisian, Kenya, a funding partnership between the NLM and the CDC is firmly in place.

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Evidence-based planning: Linking research agendas to the operational needs of control programmes

A recurring difficulty highlighted at MIM meetings during this year has been the lack of efficient mechanisms to ensure that scientific research programmes generate data that is relevant and accessible to malaria control programme activities. It is acknowledged that a broad spectrum of research priorities must continue to be pursued: creative fundamental research may generate much needed new weapons against malaria in the longer term, while more applied, operational studies can improve the application of our existing tools. It is at this more applied end of the spectrum that there has been increasing recognition of the need to encourage open dialogues between researchers, policy makers and control programme personnel to identify key data requirements and ensure that these are translated into manageable and relevant research questions.

In the following article, Professor O. Walker of the WHO Regional Office for Africa sets out some of the practical problems in developing guidelines for the use of antimalarial drugs. In the news section further details are provided on recent meetings that have been organised to begin to address some of these problems.

Towards Rational Antimalarial Drug Policies in Africa

Professor O. Walker

Background

One of the important functions of a Malaria Control Programme is to provide guidelines for rational antimalarial drug policies. This is very important in the majority of the control programmes in Africa, because of limited number of active compounds, weak health infrastructure (especially at the district levels and below where the majority of the population live), poor communication with health care facilities, costs of the drug, and the spread of drug resistant parasites.

The appearance of chloroquine resistant parasites in East Africa in 1979, has dealt a major blow to control activities in the African continent. Chloroquine was for a long time the drug of choice for treatment and prophylaxis of malaria in the majority of control programmes in Africa, possessing most of the properties desirable for a first line antimalarial drug. A drug for widespread use should be stable, have a reasonably long half life, but should be slow to induce parasite resistance to it, should have a long shelf life, be portable, easily administered and have a good toxicity profile. The cost to the patient and the programme should be affordable. Chloroquine was able to satisfy most of these requirements. It should be remembered that chloroquine has been in use in endemic countries for over forty years before clinical and laboratory evidence of resistance to the drug started to be noticed on a wide scale.

With the appearance of chloroquine resistance, many control programmes have been worried about the replacement first line antimalarial drug treatment for the uncomplicated disease. The appearance of chloroquine resistance also complicates the question of the drug of choice for prophylactic use in pregnancy. These fears are not unfounded as it has been demonstrated from control programmes in SE Asia that where other drugs have been introduced on a massive scale for the control of the malaria, the appearance of resistant parasites to these drugs was faster than it was for chloroquine (WHO, 1994). The experiences of sulfadoxine-pyrimethamine and mefloquine in Thailand are a testimony to this. This is very unwelcome news for control programmes of Africa, as they can ill afford some of the newer compounds for wide use as a first-line drug. However, where the change in first-line drug for malaria treatment is delayed, mortality and the appearance of severe forms of the disease, including severe anaemia, will escalate. The evolution of resistance therefore increased morbidity and mortality (Bloland *et al* 1991). It is important that control programmes introduce the new compound at the correct time. In addition, there are few compounds which control programmes in Africa can use on a wide scale as there are fears of high rates of side effects with use of some of the newer compounds in the market.

Efficacy of antimalarial Drugs

It is clear that control programmes should be aware of the state of the clinical efficacy of the antimalarials that are available to them. This in itself is not enough to change a policy, but is an important factor in the whole equation. The efficacy data on antimalarials will give a good indication of the direction in which the guidelines for malaria treatment would go. Data on the efficacy of antimalarials have been generated in many African countries from the sixties. Unfortunately, the majority of the data belong to researchers. The tendency by the researchers has been to utilise methods that are usually unique to them in an attempt to have the most efficacious way forward, considering the circumstances of the particular research group. This in itself is good, but has many drawbacks. In the first place, methods are not uniform. Secondly, old data may not be directly compared to new data. Instances occur in the literature where different cut off points have been used to test the efficacy of antimalarials resulting in outcomes that vary widely in the same locality.

This is unfortunate, and is not of help to control programmes who need both a historical and scientific perspective of the problem in their countries in order to use the data rationally for the update of antimalarial drug policies. In order to tackle the problem, and propose a uniform way of carrying out efficacy tests within the Ministries of Health in endemic countries, in 1994, the WHO convened an informal meeting of experts in Geneva.

As a background to this it is already well known that there are no good correlations between *in vitro* sensitivity data and *in vivo* data. The phenomenon of *in vitro* resistance appears well before clinical resistance is recognized. Therefore, any test system developed has to bear this in mind, as it is the clinical response to the drugs that is important in the eyes of practitioners in the field.

The results of the informal consultation were that a clinical system which incorporated both parasitological and clinical data in its interpretation was suggested. Minimal data point collection was also suggested in order to improve compliance with the test system. The test system suggested was one in which parasitological and clinical data were obtained from target patients over a 14 day period (Days 0, 3, 7 and 14). Additional data may be obtained as deemed necessary by the investigators. In areas where there were problems with anaemia, haemoglobin should be measured on Days 0 and 14.

Country Level Capacity Building

Capacity has been built in 31 African countries following the development of this test system in 1995. The approach is that of establishing a central training team in the Central Ministry of Health. These trainers then cascade the expertise to the districts.

In order to have a picture of the efficacy pattern of countries, sentinel sites have been chosen in each country depending on the epidemiology of the disease, population density, areas where there are large numbers of unconfirmed clinical failures and the provision of minimal facilities in the proposed test site. Each sentinel site was given a take off grant, and a minimum package of disposables for carrying out the test.

The tests have been carried out extensively in East Africa, and countries with data using this new test system include: Kenya, Tanzania, Uganda, Zambia, Namibia, Mozambique, Botswana, Rwanda, Burundi, Ethiopia, and Eritrea. The other countries in the East African sub-regional are currently collecting data according to this new test system.

This test system has confirmed that in the majority of the test sites in East and Southern Africa, there were high rates of Early and Late clinical failures with lower rates of Adequate clinical response. This is not surprising as the phenomenon of parasite resistance has been reported in East Africa for more than twenty years.

The data that have been obtained from these countries have been used to inform the process of updating antimalarial drug policies for the countries concerned. It should be stressed that the issues that concern the update of antimalarial drug policies do not revolve around efficacy tests alone. They include other factors such as provider and consumer satisfaction, patient acceptability, infrastructure of the programme and the profile of the alternative drug.

Framework

We are now in the process of pooling together experience from the African Region to develop a Regional Framework for updating antimalarial drug policy. A series of meetings have recently taken place to gain experience from the process adopted by different countries. One lesson learnt from these meetings is that it is not possible to have a framework carved out in stone for all the countries of the Region. No matter which type of framework is developed, it has to be one which puts into perspective the epidemiology, infrastructure, and the goals and targets of different malaria control programmes in the Region.

NEWS

NIH Establishes Malaria Reagent Repository

The National Institute of Allergy and Infectious Diseases (NIAID), a component of the U.S. National Institutes of Health, has awarded a seven year contract in excess of \$1 million per year to the American Type Culture Collection (ATCC) for the establishment of a Malaria Research and Reference Reagent Repository. This new repository (popularly known as MR4) will: acquire parasite, vector and relevant host cell reagents, by donation and procurement; ensure their standardization, characterization and documentation; and provide these materials to qualified investigators throughout the world at only the cost of shipping. MR4 will disseminate information about malaria reagents through print, electronic media, and attendance at major meetings. The repository will also sponsor workshops to facilitate the transfer of technology and scientific information to the malaria research community.

Establishment of this repository is one of the efforts that NIAID has undertaken in support of the Multilateral Initiative on Malaria. The Institute sponsored an initial planning meeting in November, 1997, and supported an interim repository housed at Bratton Biotech, Inc. for the past year. Under that support, some 80 malaria reagents have been acquired and expanded, and this will form the basis of the MR4. A report from the 1997 planning meeting, as well as a reagent survey form, are available on the NIAID homepage at: <http://www.niaid.nih.gov/repos/malrep.htm>.

The ATCC is a global nonprofit bioscience organization established in 1925, with the mission to acquire, authenticate, preserve, develop, and distribute biological information, technology, intellectual property, and standards for the advancement, validation, and application of scientific knowledge. The malaria repository at ATCC will be treated as a special collection, under the direction of Drs. Raymond Cypess and Yimin Wu. Within the MR4, distribution of vector reagents will be managed through the Division of Parasitic Diseases, U.S. Centers for Disease Control and Prevention (CDC). Under the NIAID contract, ATCC will form an international MR4 advisory committee to assist with prioritization of additional reagents for acquisition by the repository. ATCC will shortly establish a website for the malaria repository that will be accessible through their homepage (<http://www.atcc.org>) and linked to other prominent malaria websites.

Pregnancy Malaria and Anaemia Network (PREMA)

Following on from two international meetings on malaria and anaemia in pregnancy, held in Kisumu in 1997 and in

Liverpool in September 1998, a consensus was reached to establish a resource group and network to help prioritise this area. The goal of the PREMA network is to reduce morbidity and mortality attributable to malaria and anaemia in pregnancy and to reduce malaria attributable to low birthweight. Malaria associated anaemia in pregnant women, the related problem of low birth weight and anaemia in infants, as well as poor implementation of current knowledge into practice are major contributors to the high mortality rates in pregnant women and babies, particularly in Africa.

PREMA will establish a collaborative network to appraise existing policies and practices in countries where malaria is a public health problem. A further aim is to enhance co-operation between scientists involved in the development and testing of preventative methods, new diagnostic tools and therapeutic regimes, and policy workers involved in the design and management of malaria and anaemia control programmes. Co-operation with district medical officers involved in the implementation of antenatal, pre- and postnatal care is an essential part of the collaboration. A major goal will be to enhance the effectiveness, coverage and quality of care of existing programmes.

Several steps are required to facilitate PREMA activities. A central aspect of the initial process is to set up a database of individuals interested in the field of malaria and anaemia in pregnancy (scientists, policy makers, programme managers and health providers) from developing and developed countries as a route to facilitate acquisition of relevant information, communications between relevant persons and for dissemination of clear messages.

It is intended to publish the main findings presented at the two international malaria in pregnancy meetings, hopefully within the next six months. Reviews of the burden of disease and current practice are to be undertaken and proposals will be developed to facilitate programme monitoring and for support of implementation of recommendations stemming from the group's activities. Financial sponsorship to foster the activities of the network is required.

For more information on the PREMA network or to be registered on the database, contact :
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The New Medicines for Malaria Venture (MMV)

There is an urgent need for new drugs in the fight against malaria, but the lack of economic incentives has discouraged drugs companies from involvement in developing new families of drugs active against tropical diseases (Nature 386, 540; 1997). Thus, new mechanisms are required to develop drugs for use against malaria and other diseases primarily affecting developing countries. To address this problem, in 1997, a number of organisations, including WHO, proposed that drug companies pool resources and invest funds to launch a 'not for profit' company to develop new malaria treatments. Unfortunately,

the proposal for a public-private alliance for development of antimalarial drugs was not supported sufficiently by industrial partners in November 1997 for it to be actioned. Following substantial revisions, a new proposal, the New Medicines for Malaria Venture, has now been launched.

The MMV is a public/private sector collaboration that will be run under the RBM umbrella. It will be financed principally by the public sector and charitable bodies, with the industry providing critical other resources such as access to combinational chemical libraries and high throughput screening systems. It will be run along the lines of an industrial R&D programme. The MMV aims to register a new antimalarial drug every five years, with estimated annual costs of US\$30 million.

The proposal will operate as follows:

1. Drug discovery research will be carried out by concentrating funds on a small number of projects, each in partnership with an individual pharmaceutical company.
2. Promising drug candidates will then be taken up to proof of principle in phase 2 clinical trials by a drug development unit, financed and administered by MMV.
3. MMV will then seek industrial sponsors for co-development, through phase 3 trials, registration and marketing.

Discussions are ongoing about the final format of this venture.

The International Federation of Pharmaceutical Manufacturers Association (IFPMA), and a number of associated companies have offered their support to the proposal. Industrial commitment to MMV is essential because it will provide access to facilities which money cannot buy and also it could cut the costs of developing antimalarial drugs significantly. The UK Department for International Development (DFID) has pledged US\$5 million and the World Health Organization a further US\$3 million pa to the MMV project. A call for letters of interest is about to go out, and the first discovery research projects should be funded by mid 1999.

For information about MMV, please contact:

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Confronting the Challenge of Antimalarial Drug Resistance in Africa

In June and November, 1998, the United States Centers for Disease Control and Prevention, in collaboration with the United States Agency for International Development and the Wellcome Trust, hosted two meetings in Nairobi, Kenya, and Harare, Zimbabwe, focused on responding to the declining efficacy of antimalarial drugs and in developing rational drug use policies in sub-Saharan Africa.

To date, most of the discussion of antimalarial therapy efficacy and drug policy development has revolved around the issue of drug resistance itself. While this is an essential and central issue, there is growing recognition that many other issues, including economic considerations and patient and health care worker behavior, have significant impact on antimalarial therapy efficacy. Additionally, research and

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programmatic communities need to work more closely together than they have in the past in order to develop effective, practical, and sustainable strategies for coping with drug resistant malaria.

These meetings were designed as a forum where these practical issues could be discussed with the goal of sharing experiences and information, developing a research agenda, and formulating recommendations to help guide drug use policy development in Africa. Discussions included standardization of assessment and surveillance methodology, use of newer molecular tools for surveillance of drug resistance, managing the introduction of new antimalarial drugs into Africa, new sulfonamide-antifolate drug combinations, use of combination therapy for malaria, socio-behavioral influences, cost-effectiveness of drug use policy change, and interactions between antimalarial drug use policy and other policy elements, such as the Integrated Management of Childhood Illnesses and prevention of malaria during pregnancy. Current data on the public health impact of drug resistance, and specific country experiences with addressing antimalarial drug resistance (Malawi and Thailand) were also discussed.

Attending these meetings were about 60 participants representing 23, predominately African countries. Attendees represented both the programmatic and research communities, providing an exceptional opportunity for these two groups to discuss each others needs and priorities. The proceedings from these meetings will be published in the near future and will be used in planned efforts to develop conceptual frameworks and guidelines for developing rational antimalarial drug use policies aimed at slowing the development and minimizing the public health impact of drug resistance in Africa.

June	Infectious Diseases	Senegal	
Dec 1999	48th Annual Meeting: American Society of Tropical Medicine and Hygiene (ASTMH)	Washington, D.C., USA	ASTMH

We endeavour to ensure that all information in the newsletter is accurate. If there is any information which is missing or inaccurate, we would like to hear from you. The Wellcome Trust, as coordinator of MIM, depends on you to provide us with information on malaria activities, so we can coordinate and disseminate this information. We welcome contributions from our MIM colleagues.

Diary of Events: 1999

Date	Title/Objectives	Location	Organizers Participants
29 Jan	Sixth falciparum genome meeting	Hilton Head, USA	Sequencing consortium
Feb	Framework for Antimalarial Drug Policy Workshop	Harare, Zimbabwe	AFRO/WHO initiative funded by DFID
March	WHO/AFRO Taskforce on Malaria Control	Africa	WHO/AFRO
14-19 March	MIM African Malaria Conference	Durban South Africa	MIM
22-26 March	MIM/TDR Taskforce for Malaria Research Capability Strengthening in Africa: Grant Awards Meeting	Durban, South Africa	Co-ordinated by WHO/TDR
Spring	Drugs against parasitic diseases workshop	Montpellier France	INCO-DC COST/WHO
5-11 April	Research on Tropical Diseases and Their Control: 1. From Fundamental Research to the Planning of Malaria Control Trials (A Workshop)	Camerino, Italy	Jointly supported by the EC, DG-XII, INCO-DC Programme; UNDP; World Bank; WHO/TDR; Univ. of Camerino
19-23 April	20th African Health Sciences Congress	Accra, Ghana	Noguchi Memorial Institute for Medical Research
April	International Centers for Tropical Disease Research Meeting	Bethesda, MD, USA	NIAID
22-24	CDC Meeting on Epidemiology of	Dakar,	Organised by CDC